



**ADDITIONAL INFORMATION
DISCLOSURE
STATEMENT BY APPLICANT
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APPLICATION NO.
10/532,836

APPLICANT
Armin BREITENBACH et al.

FILING DATE
April 26, 2005

GROUP
1621

U. S. PATENT DOCUMENTS*

EXAMINER INITIAL	PATENT/PUBLICATION NUMBER	PATENT/PUBLICATION DATE	NAME	CLASS	SUBCLASS	FILING DATE*
dm	2,556,636	June 12, 1951	Nathan Sperber et al.			
dm	2,567,245	September 11, 1951	Nathan Sperber et al.			
dm	2,676,964	April 27, 1954	Nathan Sperber et al.			
dm	3,261,841	July 19, 1966	Bernard L. Zenitz			
dm	3,446,901	May 27, 1969	G. J. Macclesfield			
dm	4,988,730	January 29, 1991	Korbonits et al.			
dm	5,382,600	January 17, 1995	Jonsson et al.			
dm	5,559,269	September 24, 1996	Johansson et al.			
dm	5,922,914	July 13, 1999	Gage et al.			
dm	6,517,864	February 11, 2003	Orup Jacobsen et al.			
dm	6,310,248	October 30, 2001	Andersson et al.			
dm	6,566,537	May 20, 2003	Andersson et al.			
dm	6,630,162	October 7, 2003	Nilvebrant et al.			
dm	6,689,916	February 10, 2004	Andersson et al.			
dm	6,713,464	March 30, 2004	Meese et al.			
dm	6,770,295	August 3, 2004	Kreilgard et al.			
dm	6,783,769	August 31, 2004	Arth et al.			
dm	6,809,214	October 26, 2004	Meese			
dm	6,809,225	October 26, 2004	Donsbach et al.			
dm	6,858,650	February 22, 2005	Meese			
dm	6,890,920	May 10, 2005	Richards et al.			
dm	6,911,217	June 28, 2005	Gren et al.			
dm	2003/0124179	July 3, 2003	Jacobsen, Lene O. et al.			
dm	2004/0186061	September 23, 2004	Meese, Claus et al.			
dm	2005/0004223	January 6, 2005	Slatter, John G. et al.			
dm	2003/0152624	August 14, 2003	Aldrich et al.			
dm	2003/0158176	August 21, 2003	Richards et al.			
dm	2004/064821	April 1, 2004	Rousselle			

*- copies of U.S. references are not enclosed

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
<i>an</i>	925 468 (in German, with English translation)	March 21, 1955	DE			YES	
<i>an</i>	1 216 318 (in German, with English translation)	May 12, 1966	DE			YES	
<i>an</i>	325 571	July 26, 1989	EP				
<i>an</i>	624 117	May 27, 1949	GB				
<i>an</i>	627 139	July 29, 1949	GB				
<i>an</i>	667 852	August 23, 1995	EP				
<i>an</i>	685 696	January 07, 1953	GB				
<i>an</i>	689 835	April 08, 1953	GB				
<i>an</i>	690 274	April 15, 1953	GB				
<i>an</i>	692 931	June 17, 1953	GB				
	766,207	December 22, 1952	DE			YES	
<i>an</i>	831,799	June 7, 1996	EP				
	830,193	February 04, 1952	DE			YES	
	872,233	April 14, 1997	EP				
	948,321*	December 10, 1997	EP				
<i>an</i>	957,073	May 12, 1998	EP				
<i>an</i>	1 019 358	July 19, 2000	EP				
<i>an</i>	1,025,041	February 24, 1964	GB				
<i>an</i>	1 128 819	September 05, 2001	EP				
<i>an</i>	1 169 944	November 05, 1969	GB				
<i>an</i>	1 169 945	November 05, 1969	GB				
	WO 93/23025	November 25, 1993	PCT				
	WO 96/12477	May 02, 1996	PCT				
<i>an</i>	WO 98/03067	January 29, 1998	PCT				
<i>an</i>	WO 98/43942	October 8, 1998	PCT				
	WO 98/56359**	December 17, 1998	PCT				
<i>an</i>	WO 00/12069	March 09, 2000	PCT				
<i>an</i>	WO 00/27364	May 18, 2000	PCT				
<i>an</i>	WO 01/34139	May 17, 2001	PCT				
	WO 02/089773	November 14, 2002	PCT				
	WO 02/11702	February 14, 2002	PCT				
<i>an</i>	WO 03/002059	January 9, 2003	PCT				
	WO 03/007918	January 30, 2003	PCT				
	WO 03/020241	March 13, 2003	PCT				
<i>an</i>	WO 03/026564	April 3, 2003	PCT				
<i>an</i>	WO 03/035599	May 1, 2003	PCT				
<i>an</i>	WO 03/039464	May 15, 2003	PCT				
	WO 03/063834	August 7, 2003	PCT				
	WO 03/099268**	December 4, 2003	PCT				
	WO 03/103637	December 18, 2003	PCT				
<i>an</i>	WO 03/106421	December 24, 2003	PCT				

is it
related

unrelated

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	WO 03/021271	March 13, 2003	PCT			
	WO 04/019892	March 11, 2004	PCT			

*- English translation of claims provided

** - English translation of abstract provided

OTHER DOCUMENTS

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
ln	Abrams et al., "Tolterodine, a new antimuscarinic agent: as effective but better tolerated than oxybutynin in patients with an overactive bladder," 1998, Br. J. Urol. 81:801-810
Ln	Abstracts from the 26 th Annual Meeting of the International Incontinence Society, August 27-30, 1996, Gillberg et al., abstract 33, Neurology and Urodynamics 15:308-309
	Anderson et al., "Once daily controlled versus immediate release oxybutynin chloride for urge urinary incontinence," 1999, J. Urol. 161:1809-1812
	Andersson et al., "Pharmacological treatment of urinary incontinence," in Abrams P., Khoury S., Wein A. (Eds), <u>Incontinence, 2nd International Consultation on Incontinence</u>, Plymouth, Plymbridge Distributors Ltd, UK, Plymouth, 2002, pp 479-511
	Andersson, "Antimuscarinics for treatment of overactive bladder," 2004, Lancet Neurol. 3:46-53
	Andersson & Hedlund, "Pharmacological perspective on the physiology of the lower urinary tract," 2002, Urology 60(Suppl. 5A):13-20
	Andersson & Wein, "Pharmacology of the lower urinary tract: basis for current and future treatments of urinary incontinence," 2004, Pharmacol. Rev. 56:581-631
	Appell et al., "Prospective randomized controlled trial of extended release oxybutynin chloride and tolterodine tartrate in the treatment of overactive bladder: results of the OBJECT study," 2001, Mayo Clinic Proceedings 76:358-363
ln	Breidenbach et al., "Pharmacodynamic profiling of the novel antimuscarinic drug fesoterodine on rat bladder," 2002, Proceedings of the International Continence Society, 32:449
ln	Brynne et al., "Influence of CYP2D6 polymorphism on the pharmacokinetics and pharmacodynamics of tolterodine, 1998, Clin. Pharmacol. Thera. 63:529-539
ln	Brynne et al., "Tolterodine does not affect the human in vivo metabolism of the probe drugs caffeine, debrisoquine, and omeprazole," 1999, Br. J. Clin. Pharmacol. 47:145-150
ln	Brynne et al., "Fluoxetine inhibits the metabolism of tolterodine - pharmacokinetic implications and proposed clinical relevance," 1999, Br. J. Clin. Pharmacol. 48:553-563
ln	Brynne et al., "Ketoconazole inhibits the metabolism of tolterodine in subjects with deficient CYP2D6 activity," 1999, Br. J. Clin. Pharmacol. 48:564-572
	Cawello et al., "Multiple dose pharmacokinetics of fesoterodine in human subjects," 2002, Naunyn-Schmiedeberg's Arch. Pharmacol. 365 (Suppl. 1):428, 2002
	Chancellor et al., "A comparison of the effects on saliva output of oxybutynin chloride and tolterodine tartrate," 2001, Clinical Therapeutics 23:753-760
	Chapple & Udo, "Delay to maximum effect in overactive bladder patients treated with oxybutynin or tolterodine," 2000, European Urology 37(Suppl. 2):84, abstract 335 from the XVth Congress of the European Association of Urology, Brussels, Belgium, April 12-15, 2000
ln	Chapple et al., "Fesoterodine a new effective and well-tolerated antimuscarinic for the treatment of urgency-frequency syndrome: results of a Phase II controlled study," 2004, Proceedings of the International Continence Society, 34:142
	Clemett & Jarvis, "Tolterodine: a review of its use in the treatment of overactive bladder," 2001, Drugs & Aging 18:277-304
ln	Cole, "Fesoterodine, an advanced antimuscarinic for the treatment of overactive bladder: A safety update," 2004, Drugs of the Future 29:715-720

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Committee for Proprietary Medicinal Products, "The assessment of the potential for QT interval prolongation by non-cardiovascular medicinal products," CPMP/986/96, December 17, 1997
Am	Detrol® package insert, Pharmacia & Upjohn Co., April, 2004
	Diokno et al., "Tolterodine (Detrol®) improves incontinence and nocturia in urological based study," 1999 April, J. Urol. 161 (4 Suppl):256, abstract 987
	Ekstrom et al., "Effects of tolterodine on bladder function in healthy volunteers," Journal of Urology 153(Suppl.):394A, abstract 662 from the 19 th Annual Meeting of the American Urological Association, Las Vegas, April 23-28, 1995
	Gardner & Altman, "Confidence intervals rather than P values: estimation rather than hypothesis testing," 1986, Br. Med. J. 292:746-750
	Gillberg et al., "Tolterodine, a new agent with tissue effect selectivity for urinary bladder," 1994, Neurourology and Urodynamics 13:435-436, abstract 60B from International Continence Society 24 th Annual Meeting, Prague, Czech Republic, August 1994
	Gillberg et al., "Comparison of the in vitro and in vivo profiles of tolterodine with those of subtype-selective muscarinic receptor antagonists," 1998, European Journal of Pharmacology 349: 285-292
Am	Hills et al., "Tolterodine," 1998, Drugs 55:813-820
	Jonas et al., "Efficacy and safety of two doses of tolterodine versus placebo in patients with detrusor overactivity and symptoms of frequency, urge incontinence, and urgency: urodynamic evaluation," 1997, World J. Urol. 15:144-151
	Kang et al., "Cardiac ion channel effects of Tolterodine," 2004, J. Pharmacol. Exper. Thera. 308:933-940
	Kershen & Hsieh, "Preview of new drugs for overactive bladder and incontinence: darifenacin, solifenacin, trospium, and duloxetine," Curr. Urol. Rep. 5:359-367
Am	Klosa, "Eine Neue Synthesemethode der Darstellung von Diarylalkylaminen," 1966, Journal für Praktische Chemie 4:312-334 (in German) with English translation
Am	Klosa, "Eine Neue Synthese von Diphenylisopropylaminen," 1966, Journal für Praktische Chemie 4:335-340 (in German, with English translation)
Am	Larsson et al., "Tolterodine in the treatment of overactive bladder: analysis of the pooled phase II safety and efficacy data," 1999, Urology 53: 990-998
	Lipinski, et al., "Experimental and computational approaches to estimate solubility and permeability in drug discovery and development settings" Elsevier Advanced Drug Delivery Reviews Vol. 23, pp. 3-25, 1997
	Millard et al., "Clinical efficacy and safety of tolterodine compared to placebo in detrusor overactivity," 1999, J. Urol. 161:1551-1555
	Modiri et al., "Effect of muscarinic antagonists on micturition pressure measured by cystometry in normal, conscious rats," 2002, Urology 59:963-968
	Naerger et al., "Effect of tolterodine on electrically induced contractions of isolated human detrusor muscle from stable and unstable bladders," 1995, Neurourology and Urodynamics 14:524-526, abstract 76 from International Continence Society 25 th Annual Meeting, Sydney, Australia, October 1995
	Netzer, et al., "Screening lead compounds for QT interval prolongation" Drug Discovery Today Vol. 6, No. 2, pp.78-84, January 2001
	Nilsson et al., "Comparison of a 10 mg controlled release oxybutynin tablet with a 5 mg oxybutynin tablet in urge incontinence patients," 1997, Neurorol. Urodyn. 16:533-542
	Nilvebrant & Sparf, "Receptor binding profiles of some selective muscarinic antagonists," 1988, European Journal of Pharmacology 151:83-96
	Nilvebrant & Sparf, "Differences between Binding Affinities of some Antimuscarinic Drugs in the parotid Gland and those in the Urinary Bladder and Ileum" Acta Pharmacol. et toxicol. Vol. 53, No. 4, pp. 304-313, October 1983

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Nilvebrant et al., "The in vitro pharmacological profile of tolterodine – a new agent for the treatment of urinary urge incontinence," 1994, Neurourology and Urodynamics 13:433-435, abstract 60A from International Continence Society 24 th Annual Meeting, Prague, Czech Republic, August 1994
	Nilvebrant et al., "Tolterodine is not subtype (m1-m5) selective but exhibits functional bladder selectivity in vivo," 1996, Neurourology and Urodynamics 15:310-311, abstract 34 from the 26th Annual Meeting of the International Continence Society, Athens, Greece, August 27-30, 1996
	Nilvebrant, "Tolterodine and terodiline – different pharmacological profiles," pages 141-142, abstract 181a, from the 27th Annual meeting of the International Continence Society, Yokohama, Japan, September 1997
dm	Nilvebrant et al "Tissue distribution of tolterodine and its metabolites: low penetration into the central nervous system," 2000, European Urology 37(Suppl. 2):84, abstract 333 from the XVth Congress of the European Association of Urology, Brussels, Belgium, April 12-15, 2000
	Nilvebrant, "The mechanism of action of tolterodine," 2000, Reviews in Contemporary Pharmacotherapy 11:13-27
	Olsson et al., "Food increases the bioavailability of tolterodine but not effective exposure," 2001, J. Clin. Pharmacol. 41:298-304
	Olsson & Szamosi, "Food does not influence the pharmacokinetics of a new extended release formulation of tolterodine for once daily treatment of patients with overactive bladder," 2001, Clinical Pharmacokinetics 40:135-143
	Olsson & Szamosi, "Multiple dose pharmacokinetics of a new once daily extended release formulation versus immediate release tolterodine," 2001, Clinical Pharmacokinetics 40:227-235
	Pharmacology/Toxicology Review from Application Number 21-518, Center for Drug Evaluation and Research, pp. 1-3.
	Rentzhog et al., "Efficacy and safety of tolterodine in patients with detrusor instability: a dose ranging study," 1998, Br. J. Urol. 81:42-48
	Roy, et al., "HERG, a Primary Human Ventricular Target of the Nonsedating Antihistamine Terfenadine" Circulation Vol. 94, No. 4, pp. 817-823, August 15, 1996
	Sachse et al., "Pharmacodynamics of multiple dose treatment with the novel antimuscarinic drug fesoterodine," 2002, Nauyn-Schmiedeberg's Arch. Pharmacol. 365 (Suppl. 1):413
	Sachse et al., "Safety and pharmacokinetics of the novel bladder-selective antimuscarinic drug fesoterodine in populations of different age or gender," 2002, Proceedings of the International Continence Society , 32:441
	Sachse et al., "Safety and pharmacokinetics of the novel bladder-selective antimuscarinic fesoterodine in populations of different ethnic origin," 2003, Proceedings of the International Continence Society , 33:377
	Sachse et al., "Dose-proportional pharmacokinetics of the new antimuscarinic fesoterodine," 2003, Nauyn-Schmiedeberg's Arch. Pharmacol. 367 (Suppl. 1):446
	Sachse et al., "Pharmacodynamics and pharmacokinetics of ascending multiple oral doses of the novel, bladder-selective antimuscarinic fesoterodine," 2003, Eur. Urol. Suppl 2:111
	Sachse et al., "Concomitant food intake does not significantly influence the pharmacokinetics of the novel, bladder-selective antimuscarinic fesoterodine," 2004, Proceedings of the International Continence Society , 34:580
	Sachse et al., "Safety, tolerability and pharmacokinetics of fesoterodine in patients with hepatic impairment," 2004, Proceedings of the International Continence Society , 34:585
	Sachse et al., "Safety, tolerability and pharmacokinetics of fesoterodine after co-treatment with the potent cytochrome P450 3A4 inhibitor ketoconazole," 2004, Proceedings of the International Continence Society , 34:586
	Sachse et al., "Clinical pharmacological aspects of the novel bladder-selective antimuscarinic fesoterodine," 2004, Progrès en Urologie , 14 (Suppl. 3):58
	Stahl et al., "Urodynamic and other effects of tolterodine: a novel antimuscarinic drug for the treatment of detrusor overactivity," 1995, Neurourol. Urodyn. 14:647-55

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
		Teuvo et al "Extended release tolterodine compared with immediate release tolterodine for the treatment of overactive bladder," 2000, European Urology 37(Suppl. 2):84, abstract 334 from the XVth Congress of the European Association of Urology, Brussels, Belgium, April 12-15, 2000
		Van Kerrebroeck et al., "Tolterodine once daily: superior efficacy and tolerability in the treatment of the overactive bladder," 2001, Urology 57:414-421
		Van Kerrebroeck et al., "Clinical efficacy and safety of tolterodine compared to oxybutynin in patients with overactive bladder," 1997, Neurourol. Urodyn. 16:478-479, abstract no. 91 from the 27th Annual meeting of the International Continence Society, Yokohama, Japan, September 1997
		Versi et al., "Dry mouth with conventional and controlled release oxybutynin in urinary incontinence," 2000, Obstet. Gynecol. 95:718-721
		Wefer et al., "Tolterodine: an overview," 2001, World Journal of Urology 19:312-318

EXAMINER <i>Lalitha Nagubandi</i>	DATE CONSIDERED <i>05/29/06</i>
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	